

U.S. Department of Health & Human Services



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NIH begins testing H7N9 avian influenza vaccine candidate

Possible role for adjuvants to be examined

Researchers at nine sites nationwide have begun testing in humans an investigational H7N9 avian influenza vaccine. The two concurrent Phase II clinical trials, sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, are designed to gather critical information about the safety of the candidate vaccine and the immune system responses it induces when administered at different dosages and with or without adjuvants, substances designed to boost the body's immune response to vaccination.

Human cases of H7N9 influenza first emerged in China in February 2013, with the majority of reported infections occurring in the spring. As of Aug. 12, 135 confirmed human cases, including 44 deaths, have been reported by the World Health Organization. Most of these cases involved people who came into contact with infected poultry. Although no H7N9 influenza cases have been reported outside of China and the virus has not demonstrated sustained person-to-person transmission, there is concern that it could mutate to pose a much greater public health threat.

"H7N9 avian influenza virus — like all novel influenza virus strains to which people have not been exposed — has the potential to cause widespread sickness and mortality," said NIAID Director Anthony S. Fauci, M.D. "We are now testing a vaccine candidate with and without adjuvant in an effort to prepare for and, hopefully, protect against this possibility."

The two clinical trials, which will enroll healthy adults ages 19 to 64, will evaluate an investigational H7N9 vaccine developed by Sanofi Pasteur. The candidate vaccine was made from inactivated H7N9 virus isolated in Shanghai, China in 2013. Adjuvants are being tested with the investigational vaccine because previous vaccine research involving other H7 influenza viruses has suggested that two doses of vaccine without adjuvant may not produce an immune response adequate to provide effective protection. In pandemic situations, adjuvants also can be used as part of a dose-sparing strategy, which would allow production of more doses of vaccine from the available supply of the viral antigen, thereby allowing a greater number of people to be vaccinated more quickly.

The first clinical trial, led by Mark J. Mulligan, M.D., of Emory University in Atlanta, will enroll as many as 700 study participants who will be randomly assigned to one of seven groups (up to 100 participants in each group). Each group will receive two equivalent dosages (3.75 micrograms [mcg], 7.5 mcg, 15 mcg or 45 mcg) of the candidate vaccine, approximately 21 days apart. Five of the groups will receive the vaccinations along with MF59 adjuvant, developed by Novartis Vaccines and Diagnostics.

Of these five groups, three will receive adjuvant with both vaccinations; one group of participants will receive adjuvant only with the first vaccination; and another group of participants will receive adjuvant only with the second vaccination. Two groups of participants will not receive adjuvant. The MF59 adjuvant that is being tested is also contained in the Flud seasonal influenza vaccine currently licensed in Europe and Canada for use in people age 65 years or older.

The second trial, led by Lisa A. Jackson, M.D., M.P.H., of Group Health Research Institute in Seattle, will enroll as many as 1,000 participants. Each participant will be randomly assigned to one of 10 groups (up to 100 participants per group) and will receive two equivalent doses (same dosages as the other trial) of the investigational H7N9 vaccine given 21 days apart.

Seven of these groups will receive the vaccinations either with or without AS03 adjuvant, developed by GlaxoSmithKline Biologics. Two groups will receive their first vaccination with AS03 or MF59 adjuvant and then receive the alternate adjuvant at time of second vaccination. One group will receive the MF59 adjuvant at both vaccinations. The AS03 adjuvant that is being tested was used in a 2009 H1N1 influenza vaccine, Pandemrix, used in several European countries during the 2009-2010 H1N1 influenza pandemic.

In both studies, which are expected to conclude in December 2014, a panel of independent experts will closely monitor safety data at regular intervals throughout the trial.

The vaccine studies are being conducted at the eight NIAID-funded Vaccine and Treatment Evaluation Units: Baylor College of Medicine, Houston; Children's Hospital Medical Center, Cincinnati; Emory University, Atlanta; Group Health Cooperative, Seattle; Saint Louis University, St. Louis; University of Iowa, Iowa City; University of Maryland School of Medicine, Baltimore; and Vanderbilt University, Nashville. The University of Texas Medical Branch at Galveston will conduct the trial as a subcontractor to Baylor College of Medicine.

Further information about both clinical trials can be found at <http://www.ClinicalTrials.gov> using the identifiers: NCT01938742 and NCT01942265.

For more information, visit NIAID's Influenza Web portal. For U.S. government information on avian and pandemic influenza, see <http://www.Flu.gov>.

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